JUN 15 2010

Nidacon

Flöjelbergsgatan 16 B
SE-431 37 Mölndal
Sweden
Tel: +46-31-703 06 30
Fax: +46-31-40 54 15
E-mail: contact@nidacon.se

510(k) Summary

Tradename: VitriBlast™ and ThermoBlast™

Common Name: Solutions for the vitrification of human blastocysts and for the thawing of vitrified human blastocysts.

Classification name: Reproductive Media (21 CFR, 886.6180, Product code: MQL)

Intended use:

- VitriBlast is intended for ultra-rapid freezing (vitrification) of human blastocysts. This kit is designed for use with Nidacon's ThermoBlast kit for optimal recovery of specimens. This product is used for assisted reproduction-technology procedures.
- ThermoBlast is intended for the recovery of human blastocysts that have undergone ultra-rapid freezing (vitrification) using Nidacon's VitriBlast kit. It is designed for optimal thawing and recovery of the specimens. This product is used for assisted reproduction-technology procedures.

Description:
VitriBlast consists of 5 separate vials as described hereunder:
- VitriBlast 1: 10mL based on PureSperm Wash (K002630), with additional hSA.
- VitriBlast 2: 10mL same as solution 1, plus Ethylene glycol (7.5%) and DMSO (7.5%) both provided for separate addition.
- VitriBlast 3: 10mL same as solution 1, including Sucrose (0.67 M) and Ficoll (0.14 mM), plus Ethylene glycol (15%) and DMSO (15%), both provided for separate addition just prior to use.

ThermoBlast consists of 4 separate, 10 mL vials as follows:
- ThermoBlast 4: based on VitriBlast 1 with additional sucrose (0.33 M).
- ThermoBlast 5: based on VitriBlast 1 with additional sucrose (0.21 M).
- ThermoBlast 6: the same as VitriBlast 1 (2 vials).

Device function/Scientific Concept
During the cryopreservation of embryos, they are at risk of injury from chilling and crystallisation, the toxicity of the cryo protectant, extracellular ice, intracellular ice, fracture damage, osmotic swelling and osmotic shrinkage. To obtain high rates of survival, all these problems must be circumvented.

Among the injuries, the damage caused by the formation of intracellular ice crystals during cooling and or warming is one of the greatest obstacles to overcome. It is desirable to freeze without forming crystals within the cell and this can be achieved by vitrification (glass transition without crystals). Vitrification is ultimately the result of the fact that a liquid cannot have more order than its corresponding crystal. As the temperature of a liquid substance is lowered, its entropy is reduced more rapidly than the entropy of the corresponding crystalline form of the substance. If the liquid does not freeze, a thermodynamic conundrum is approached as the entropy of the liquid approaches the entropy of the crystal.

Nidacon

Flöjelbergsgatan 16 B
SE-431 37 Mölndal
Sweden
Tel: +46-31-703 06 30
Fax: +46-31-40 54 15
E-mail: contact@nidacon.se

For preventing intracellular ice from forming, rapidly permeating cryo-protectants, such as ethylene glycol and DMSO, are suitable since the rapid permeation by these cryo-protectants is essential to vitrify the embryo. To prevent osmotic swelling during removal of the cryoprotectants during thawing, rapidly permeating agents are also suitable, because the faster the diffusion of the intracellular cryo-protectant out of the cell, the lower the risk of osmotic over-swelling. Ficoll is included as a non-permeating polymer (macromolecules promote vitrification) because it has high solubility, low viscosity and low toxicity. It has been shown that even large amounts of Ficoll are virtually non-toxic. A large amount of polymer occupies a significant proportion of the solution volume. Therefore, its inclusion must increase the proportion of permeating cryoprotectant per water volume. This may be one mechanism that promotes vitrification of the solution. Our solution contains not only ethylene glycol and Ficoll, but also sucrose as a non-permeating small sugar which has considerable osmotic effect. The inclusion of sucrose is quite effective at reducing the apparent toxicity of ethylene glycol, probably because sucrose promotes the shrinkage of embryos, thereby restricting excess permeation of ethylene glycol and, thus, reducing its toxic effect. In addition, sucrose helps prevent over-swelling during thawing and the removal of the ethylene glycol.

Products claimed for substantial equivalence:

- VitKit-Freeze and VitKit-Thaw from Irvine Scientific (K060168) (DMSO, Ethylene glycol, Sucrose)
- Vitri Freeze Kit from FertiPro (K070135) (same as above + Ficoll)

Comparison to predicate device

The two predicate devices were compared in the following areas and were found to have similar technological characteristics:

Nidacon's products use the same cryoprotectants (DMSO, Ethylene glycol and Sucrose) but the devices have different base media. Irvine uses medium 199 and FertiPro uses PBS, while Nidacon uses PureSperm® Wash. We have also added Ficoll, a polymer macromolecule (as also used in the FertiPro product). Nidacon has the same concentrations of the cryoprotectants Ethylene glycol (7.5%) and DMSO (7.5%) in vitrification solution number 2 and 15% of Ethylene glycol (EG) and DMSO in vitrification solution number 3, as with the Irvine products.

The EG and DMSO in the Nidacon kit are to be added by the clinic just prior to use. In Irvine's product, these compounds are added during production. All three products contain Human Serum Albumin (hSA). Nidacon has not included any vitrification device but, instead, provides recommendations for both closed and open systems (open systems only outside US). Irvine's Vitrification media contain antibiotics, which are not present in either Nidacon's or Fertipro's products.

Nidacon

Flöjelbergsgatan 16 B
SE-431 37 Mölndal
Sweden
Tel: +46-31-703 06 30
Fax: +46-31-40 54 15
E-mail: contact@nidacon.se

	Nidacon	Irvine	FertiPro
Intended use	VitriBlast is intended for ultra-rapid freezing (vitrification) of human blastocysts. This kit is designed for use with Nidacon's ThermoBlast kit for optimal recovery of specimens. This product is used for ART procedures. ThermoBlast is intended for the recovery of human blastocysts that have undergone ultra-rapid freezing (vitrification) using Nidacon's VitriBlast kit. It is designed for optimal recovery of specimens. This product is used forART procedures.	VitriKit Freeze is intended for ultra-rapid freezing and containment of human blastocysts for ART procedures VitriKit –Thaw is intended for the recovery of human blastocysts that have undergone ultra-rapid freezing and containment using Vitri Kit - Freeze	VitriFreeze is intended for ultra-rapid freezing using of human blastocysts for ART procedures VitriThaw is intended for the recovery of human blastocysts that have undergone ultra-rapid freezing using VitriFreeze, for ART procedures
Formulation	Hepes buffered media containing ethylene glycol, DMSO, Ficoll, Sucrose and HSA	Media 199 containing ethylene glycol, DMSO, Sucrose, HSA and antibiotics	PBS containing ethylene glycol, DMSO, Sucrose, Ficoll and HSA
Shelf-life	6 months	1 year	6 months

The products from the three companies (Nidacon, Irvine and FertiPro) are based on the same technologies and scientific concepts, and can therefore be considered equivalent.

Performance testing

Bench

Satisfactory safety of the products has been determined during all batch productions and during establishment of the shelf-life. The following tests were utilised:

- pH testing
- Osmolality control
- One cell MEA
- MEA according to intended use
- Endotoxin level measurements

Animal Non-Clinical Trials

Nidacon applies two different types of MEA testing, one according to the FDA recommended method (2 cell MEA %blast 96 h) and one where the performance of the solutions is evaluated (testing according to intended use). Both results will be stated in the QA-Certificate and the product insert.

Nidacon

Flöjelbergsgatan 16 B
SE-431 37 Mölndal
Sweden
Tel: +46-31-703 06 30
Fax: +46-31-40 54 15
E-mail: contact@nidacon.se

Human Clinical Trials

Fertility Clinic: The Fertility Centre at Carlanderska Hospital in Gothenburg, Sweden, was started in 1987 by Dr. Matts Wikland. Since the start, they have been one of the world leading clinics in the ART field. They were the first European laboratory to be accredited according to ISO/IEC 17025 in 1998. The clinic has been using the vitrification methodology since 2005. The products from Nidacon called VitriBlast™ and ThermoBlast™ were developed during scientific collaboration between Nidacon International AB and The Fertility Centre.

Patient group: When going through an IVF treatment, one might have excess potential blastocysts which need to be stored for the patient/couple for possible future treatment in case of failure of pregnancy or the desire for more children. Today these excess blastocysts are routinely stored by cryo-preservation. Nidacon became the manufacturer of the vitrification media used at The Fertility centre, using their same recipe, two years after the clinical testing was commenced, and had become routine at the clinic. Therefore, no specific test group was selected for the Nidacon vitrification media.

Test period: Today VitriBlast™ and ThermoBlast™ are the only vitrification solutions used in patient treatments at The Fertility Centre and the figures below illustrate all results from the clinic since 2007, when the solutions made by Nidacon were first used.

Method; The protocol is according to the package insert for VitriBlast™ and ThermoBlast™, and using the cryo-loop as device. A more comprehensive methodological description using the cryo-loop is attached.

Results from Fertility Centre;

Age of woman	Average : 35,9 range 24-45
Infertility Reason	1/3 female factors, 1/3 male factors and 1/3 unexplained infertility
No of thawed blastocysts	424
No of survived	391 (391/424= 92%)
No of transferred	391
No of transfers	385
No of single embryo transfers	379 (98.4%)
No of gestational sacs	178
Implantation rate	178/391 = 45.5%
No of clinical pregn,	176
Pregnancy rate	176/385= 45.7%
Abortion rate	9 % (calculated by born babies – amount positive heart beats week 6-7)

1) It is standard procedure at the Göteborg clinic to use blastocysts for vitrification (usually at Day 5 or 6).
2) All the blastocysts used for vitrifying were artificially shrunk by laser.

To date, 125 babies have been born using this freezing technique and these Nidacon formulations, VitriBlast™ and ThermoBlast™. No malformations in the offspring have been observed and no pregnancy terminations have occurred. Moreover, there were no multiple pregnancies.

Based on the clinical data presented and our experience with VitriBlast™ and ThermoBlast™, we feel that the safety and effectiveness of the products for their intended use are shown in the present submission and the products are substantially equivalent to the predicate devices from Irvine (K060168) and FertiPro ((K070135). A follow up study was performed on the children born after using Nidacon's Vitrification media, and from this study it

Nidacon

Flöjelbergsgatan 16 B
SE-431 37 Mölndal
Sweden
Tel: +46-31-703 06 30
Fax: +46-31-40 54 15
E-mail: contact@nidacon.se

could be concluded that there were no adverse effects or complications, and that Nidacon's products were better than clinically equivalent.

Additional Information
For the release of each production batch of this product, an endotoxin test, two mouse embryo assays and sterility testing will be performed. The results will be reported on a Quality Assurance Certificate available for all batches.

Collapsing of blastocysts prior to Vitrification
Artificial shrinkage of expanded and hatching blastocysts will be recommended. However, this technique is optional when vitrifying early blastocysts with smaller blastocoelic cavities.

Conclusion
The testing performed, using the animal model and the testing in the clinic setting proves that these products meet the design requirements, and that they have substantial equivalence to the Irvine and FertiPro products and is therefore suitable for the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

NidaCon International AB
c/o Daniel Kamm, P.E.
Submission Correspondent
Kamm & Associates
8870 Ravello Court
NAPLES FL 34114

JUN 15 2010

Re: K092107
Trade/Device Name: VitriBlast and ThermoBlast Reproductive Media
Regulation Number: 21 CFR §884.6180
Regulation Name: Reproductive media and supplements
Regulatory Class: II
Product Code: MQL
Dated: May 25, 2010
Received: June 2, 2010

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

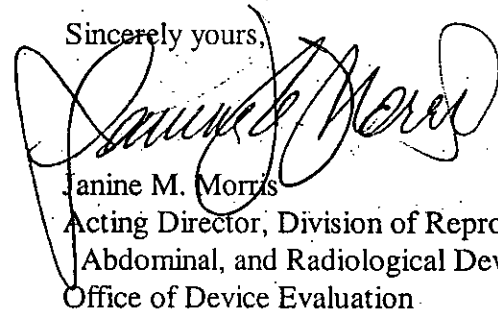
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092107

Device Name: VitriBlast

Indications For Use:
VitriBlast is intended for ultra-rapid freezing of human blastocysts. This kit is designed for use with Nidacon's ThermoBlast Thaw Kit for optimal recovery of specimens.
This product is used for Assisted Reproductive Technology (A.R.T.) procedures.

Prescription Use _X_ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092107

Indications for Use

510(k) Number (if known): K092107

Device Name: ThermoBlast

Indications For Use:
ThermoBlast is intended for the recovery of human blastocysts that have undergone ultra-rapid freezing using Nidacon's VitriBlast Kit. It is designed for optimal recovery of specimens. This product is used for Assisted Reproductive Technology (A.R.T.) procedures.

Prescription Use _X_ AND/OR Over-The-Counter Use ____.
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092107